

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel.	:	CIVIL ACTION
MATTHEW CESTRA, et al.	:	NO. 14-1842
	:	
v.	:	
	:	
CEPHALON, INC., et al.	:	
	:	
O'NEILL, J.	:	June 3, 2015

**MEMORANDUM**

Plaintiff Matthew Cestra brings this action against defendants Cephalon, Inc. and John Does #1-100 to recover damages and civil penalties on behalf of the United States as a qui tam relator pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729, et. seq. and analogous state laws. Presently before me are Cephalon's motion to dismiss relator's second amended complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b) (Dkt. No. 1-34), relator's opposition (Dkt. No. 1-38), Cephalon's reply (Dkt. No. 1-45) and the parties' supplemental briefs. Dkt. Nos. 11, 16, 18. For the reasons that follow, I will grant Cephalon's motion in part and deny it in part.

**BACKGROUND**

Treanda is a chemotherapy drug the FDA approved in October, 2008 as a treatment for indolent non-Hodgkins lymphoma (iNHL). Dkt. No. 1-30 at ¶ 3. Treanda was approved as a second-line treatment, meaning it was FDA approved only for patients whose cancer progressed after treatment with another regimen. Id. Relator is a former employee of Cephalon. Id. at ¶ 19. Relator alleges that as early as December, 2007, Cephalon promoted Treanda off-label for front-line, rather than second-line, treatment of iNHL, a use not approved by the FDA. Id. at ¶ 116. Relator asserts this off-label promotion caused the submission of false claims for reimbursement

from government health programs. Id. at ¶¶ 13-14, 75-190. Relator also alleges that Cephalon illegally paid kickbacks to physicians in order to further its off-label promotion scheme, id. at ¶¶ 191-254, violated its obligations to the government under its Corporate Integrity Agreement, id. at ¶¶ 341-377, conspired with physicians to further its off-label promotion scheme, id. at ¶¶ 434-36, and retaliated against him for investigating and reporting his concerns regarding Cephalon's conduct. Id. at ¶¶ 422-26. I will briefly summarize relator's factual allegations.

## **I. Off-Label Marketing Allegations**

Relator alleges that Cephalon used a German clinical study, the Rummel study, to promote Treanda off-label even though it knew that the Rummel study was deeply flawed and would be contradicted by Cephalon's own clinical study, known as the BRIGHT study, that began in April, 2009. Id. at ¶¶ 4-6, 82-114. Relator alleges that the BRIGHT study, while purportedly meant to help Cephalon pursue FDA approval of Treanda for front-line treatment of iNHL, was inadequate for that purpose and instead was meant to "preserve the illusion of [Cephalon's] confidence in the Rummel study" and justify continued off-label promotion of Treanda. Id. at ¶¶ 88-91. On February 22, 2011, relator allegedly attended a planning meeting where Cephalon senior management agreed to deceive the market regarding Treanda's effectiveness as a front-line treatment for iNHL. Id. at ¶¶ 93-114.

Relator alleges that Cephalon carried out its off-label marketing scheme through several means: sales force presentations and meetings, including allegations of the specific time, location, individual participants and content of the meetings, in which Cephalon allegedly used the Rummel study to promote Treanda off-label, id. at ¶¶ 118-32; continuing medical education programs (CME's), including specific allegations regarding slide decks, meetings, individual presenters and funding to promote Treanda off-label, id. at ¶¶ 133-149; speaker programs,

including specific allegations regarding the presenting physicians, number of times they presented, amounts paid to presenting physicians and slide decks used to promote Treanda off-label, id. at ¶¶ 150-55; advisory boards through which Cephalon allegedly paid physicians \$4,000 per day to allow Cephalon to promote Treanda to them for off-label use, id. at ¶¶ 156-61; market studies, specifically a study questionnaire and three studies, that were allegedly used to promote the Rummel study to oncologists, id. at ¶¶ 162-72; false and misleading minimization of safety risks associated with using Treanda off-label, id. at ¶¶ 173-78; and filing for FDA approval for front-line use of Treanda as a ruse to continue off-label promotion. Id. at ¶¶ 179-88.

## **II. Kickback Allegations**

Relator alleges that Cephalon also used illegal kickbacks to induce the prescription of Treanda off-label. Id. at ¶¶ 191-254. In particular, relator alleges that Cephalon paid kickbacks through the following means: payments to continuing medical education providers, id. at ¶¶ 191-94; payments to promotional speakers in the form of speaker fees, id. at ¶¶ 195-99; financial inducements to group purchasing organization (GPO's) and payments to GPO's to allow Cephalon to market off-label directly to GPO members, id. at ¶¶ 200-14; payments of honoraria and travel, hotels and meals to physicians to attend advisory boards, id. at ¶¶ 215-18; free reimbursement services provided directly to physicians through the Cephalon Oncology Reimbursement (CORE) program, id. at ¶¶ 219-237; payments in the form of advertising expenditures to procure favorable treatment of Treanda in medical journals, id. at ¶¶ 238-41; and payments to drug compendia to conduct clinical studies of Treanda in order to induce changes in the government's labeling determinations and in order to induce off-label prescription by physicians. Id. at ¶¶ 242-54.

### **III. Corporate Integrity Agreement Allegations**

In 2008 Cephalon entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services. Id. at ¶ 353. Relator alleges that by failing to report its alleged off-label promotion and payment of illegal kickbacks, Cephalon “engaged in a deliberate plan to knowingly submit false reports to the OIG—as required per the terms of the CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether.” Id. at ¶ 342. Relator asserts that this conduct “avoided or decreased an obligation to pay or transmit money or property to the Government.” Id. In particular, relator alleges that Cephalon avoided its obligations under the CIA by manipulating internal audits, failing to report the use of off-label promotional slide-decks and failing to report the payment of kickbacks. Id. at ¶¶ 341-377.

### **IV. Conspiracy Allegations**

Relator alleges that Cephalon conspired with the healthcare professionals identified in his second amended complaint to violate the FCA by causing or submitting false claims for reimbursement of Treanda to government programs. Id. at ¶ 435.

### **V. Retaliation Allegations**

Relator contends that Cephalon retaliated against him on two occasions when he internally reported allegedly illegal promotional activities and kickback schemes to Cephalon’s compliance department. Id. at ¶¶ 422-423. Relator alleges he was locked out of meetings he had previously attended and was effectively forced to resign because of his internal reporting. Id. at ¶¶ 423-425.

## STANDARD OF REVIEW

### I. Rule 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). Typically, “a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations,” though plaintiff’s obligation to state the grounds of entitlement to relief “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). “Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all of the allegations in the complaint are true (even if doubtful in fact).” Id. (citations omitted). This “simply calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of” the necessary element. Id. at 556. The Court of Appeals has made clear that after Ashcroft v. Iqbal, 556 U.S. 662 (2009), “conclusory or ‘bare-bones’ allegations will no longer survive a motion to dismiss: ‘threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.’ To prevent dismissal, all civil complaints must now set out ‘sufficient factual matter’ to show that the claim is facially plausible.” Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009), quoting Iqbal, 556 U.S. at 678. The Court also set forth a two part-analysis for reviewing motions to dismiss in light of Twombly and Iqbal:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a “plausible claim for relief.”

Id. at 210-11, quoting Iqbal, 556 U.S. at 679. The Court explained, “a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” Id., citing Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234-35 (3d Cir. 2008). “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” Iqbal, 556 U.S. at 679, quoting Fed. R. Civ. P. 8(a)(2).

## **II. Rule 9(b)**

Federal Rule of Civil Procedure 9(b) provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). “FCA claims must be pleaded with particularity in accordance with [Rule] 9(b).” U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004). The Court of Appeals has elaborated that “Rule 9(b) requires plaintiffs to plead with particularity the ‘circumstances’ of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior.” Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). Thus, “the purpose of Rule 9(b) is to provide defendants with fair notice of the plaintiffs’ claims . . . .” Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156 (3d Cir. 2014) (adopting a more lenient pleading requirement in false claims actions under Rule 9(b) because the touchstone consideration is fair notice).

## **DISCUSSION**

Plaintiff has filed this action as a qui tam relator under 31 U.S.C. § 3730(b), which provides that a private person may bring an action on behalf of the government to enforce the

FCA. “On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009” (FERA), which amended the FCA. Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 15 (D.N.J. 2011). Relator alleges violations of § 3729(a)(1)(A)<sup>1</sup> for presenting or causing the submission of false claims to the government, § 3729(a)(1)(B)<sup>2</sup> for making or using a false record or statement to cause the submission of false claims to the government, § 3729(a)(1)(C)<sup>3</sup> for conspiracy, § 3729(a)(1)(G)<sup>4</sup> for avoiding or decreasing an obligation to pay the government, § 3730(h) for retaliation and also asserts claims under analogous state laws. Cephalon moves to dismiss relator’s claims for failure to plead fraud with particularity under Rule 9(b) and for failure to state a claim under Rule 12(b)(6).

**I. Claims under § 3729(a)(1)(A) and § 3729(a)(1)(B)**

Section 3729(a)(1)(A) gives rise to liability where one “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” by the government. 31 U.S.C. § 3729(a)(1)(A). Thus, the elements of a prima facie claim under § 3729(a)(1)(A) are: “(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.” Schmidt, 386 F.3d at 242 (citations omitted) (discussing pre-FERA provision).

Section 3729(a)(1)(B) gives rise to liability where one “knowingly makes, uses, or causes to be

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<sup>1</sup> Relator alleges violations of 31 U.S.C. § 3729(a)(1) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 1-30 at ECF 136 n.1. “Neither party addresses” the separate versions of the statute or how they might affect my analysis here. Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 15 (D.N.J. 2011).

<sup>2</sup> Relator alleges violations of 31 U.S.C. § 3729(a)(2) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 1-30 at ECF 136 n.2. “Neither party addresses” the separate versions of the statute or how they might affect my analysis here. Foglia, 830 F. Supp. 2d at 15.

<sup>3</sup> Relator alleges violations of 31 U.S.C. § 3729(a)(3) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 1-30 at ECF 137 n.3.

<sup>4</sup> Relator alleges violations of 31 U.S.C. § 3729(a)(7) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 1-30 at ECF 137 n.4.

made or used, a false record or statement material to a false or fraudulent claim” from the government. 31 U.S.C. § 3729(a)(1)(B). Thus, under § 3729(a)(1)(B) a plaintiff must allege that the “defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved.” Schmidt, 386 F.3d at 242 (discussing pre-FERA provision).

#### **A. Off-Label Promotion**

Cephalon argues that relator fails to adequately plead an off-label promotion scheme with particularity under Foglia. See Dkt. No. 18 at ECF 2. In Foglia, the Court of Appeals held that in order to satisfy the particularity standard under Rule 9(b), a plaintiff bringing an FCA claim does not have to allege actual submission of a false claim but must only “provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” 754 F.3d at 157-58 (citations omitted). Thus, the standard is two-fold: to satisfy Rule 9(b) first relator must allege particular details of a scheme to submit false claims and second he must provide reliable indicia that lead to a strong inference the scheme caused claims to be actually submitted for reimbursement by government health programs.

Relator alleges with particularity the “who, what, when, where and how of the events at issue.” In re Rockefeller Ctr. Props. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal citations omitted) (discussing pleading standard under Rule 9(b)). Relator identifies the “what” and “how” with particularity by alleging Cephalon’s scheme to promote Treanda off-label as a first-line treatment of iNHL and identifying the specific methods of off-label promotion, such as the knowing misrepresentation of the Rummel study through various means including pre-launch promotion of Treanda, sales representative presentations, speaker programs, continuing medical

education programs, advisory boards, minimizing safety risks and using market research studies to expose physicians to information about using Treanda off-label. See Dkt. No. 1-30 at ¶¶ 115-88. Relator identifies the “who” of specific departments and individuals that participated in creating and furthering the scheme, id. at ¶¶ 93-114, and the specific doctors and organizations that participated in the various methods of off-label promotion such as speaker programs or continuing medical education. See e.g., id. at ¶ 152 (identifying promotional speakers by name, practice, number of speaking engagements and compensation), ¶ 143 (identifying CME programs funded by Cephalon including presenting physicians, the location of presentations and the content of the allegedly off-label message). Relator pleads the “when” and “where” of the scheme by alleging the specific meetings and conversations in which off-label promotion occurred or where Cephalon furthered its off-label promotion scheme. See e.g., id. at ¶¶ 116, 118-19, 121, 137, 143, 177, 179. Thus, relator has pled with particularity the details of a scheme to submit false claims to the government for reimbursement. Foglia, 754 F.3d at 157-58.

The next question is whether relator has paired those particular details of Cephalon’s alleged scheme to submit false claims with “reliable indicia that lead to a strong inference that claims were actually submitted.” Foglia, 754 F.3d at 157-58. Cephalon contends that there is no strong inference that claims were actually submitted due to its alleged off-label promotion because relator has not offered a single, particularized fact that any physician prescribed Treanda off-label as a result of Cephalon’s off-label promotion rather than as a result of reading the medical literature available to physicians generally. See Dkt. No. 18 at ECF 2-3. Of course Rule 9(b) does not, “as a matter of law, require that [relator] allege specific examples of false claims” but relator must still provide some other reliable indicia of actual submission. Hericks v. Lincare Inc., No. 07-387, 2014 WL 1225660, at \*9 (E.D. Pa. Mar. 25, 2014).

I find that relator has alleged reliable indicia that permit a strong inference false claims were actually submitted as a result of Cephalon's off-label promotion efforts because he alleges with particularity (1) the success of Cephalon's off-label marketing scheme in increasing off-label Treanda sales and (2) efforts by Cephalon to ensure that off-label prescriptions were actually reimbursed by government programs. Relator's off-label promotion claim can withstand Cephalon's motion to dismiss because the combination of detailed allegations that Cephalon's off-label promotion drove increased sales of Treanda and the existence of a specific program to ensure that those off-label sales resulted in reimbursement from the government are sufficiently reliable indicia that Cephalon's promotion actually caused the submission off-label claims to the government for reimbursement.

First, regarding the increased sales of Treanda due to Cephalon's off-label marketing scheme, relator alleges that Cephalon's "Treanda Brand Review" slide decks dated July 22, 2010, state that Cephalon's advisory boards alone generated five million dollars that year in new, off-label sales of Treanda. Dkt. No. 1-30 at ¶¶ 160-61. As another example, relator asserts that Cephalon Oncology estimated its In-Practice Programs for physicians, through which Treanda was allegedly promoted off-label and Cephalon allegedly paid kickbacks, yielded a 12:1 return on investment of \$420,000 per program in 2010. Id. at ¶ 208. Relator specifies the impact on monthly sales of Treanda through seven cancer centers that Cephalon itself allegedly identified resulted from their participation in Cephalon's In-Practice Program. Id.

Second, relator alleges that Cephalon used its CORE Program to ensure that off-label prescriptions would be reimbursed by government programs. Id. at ¶¶ 219-37. Relator asserts that Cephalon spent over three million dollars per year to provide reimbursement support to doctors and office managers submitting claims to government programs. Id. at ¶ 231. Relator

asserts that at Cephalon's National Sales Meeting in Dallas, Texas on September 20, 2010, Cephalon's Senior Director of Pricing and Reimbursement stated that the CORE Program had an 82 percent success rate in overturning adverse coverage decisions. Id. at ¶ 232. Relator also alleges specific facts suggesting Cephalon understood the CORE Program was being used to overturn coverage denials of off-label prescriptions of Treanda. Id. at ¶ 233. Relator's CORE Program allegations serve as a strong indication that Cephalon's alleged off-label promotion actually resulted in the submission of false claims for reimbursement from government programs, since the CORE program was allegedly designed to ensure increased reimbursement for off-label prescriptions likely to be denied coverage under government programs. Finally, both the sales increase and CORE program allegations are sufficiently reliable because they are not conclusory or speculative, but rather are detailed allegations that rely upon references to Cephalon's own documents and statements.

Relator has alleged reliable indicia giving rise to a strong inference under Rule 9(b) that Cephalon's off-label marketing scheme caused the submission of false claims to the government. Thus, I will deny Cephalon's motion to dismiss relator's off-label promotion claims.

## **B. Kickback Claims**

Cephalon also contends that relator has failed to sufficiently plead how kickbacks it paid to physicians caused off-label prescriptions of Treanda. See Dkt. No. 18 at ECF 4. The Anti-Kickback Act provides in relevant part:

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility,

service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320(a)-7(b)(2). “[F]alsely certifying compliance with the . . . Anti-Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA,’ and can stand upon a theory of implied false certification.” U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 373 (E.D. Pa. 2014), citing U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 313 (3d Cir. 2011). Under Rule 9(b), kickback allegations must provide the “essential factual background regarding th[e] claim” such as “facts regarding specific patients, doctors, or offices.” Hericks, 2014 WL 1225660, at \*12. To withstand dismissal the relator must also allege adequate facts supporting causation between the provision of kickbacks and the prescription of the drugs at issue. See U.S. ex rel. Lampkin v. Johnson & Johnson, Inc., No. 08-05362, 2013 WL 2404238, at \*5 (D.N.J. May 31, 2013). Cephalon primarily relies upon two cases, Hericks and U.S. ex rel. Joseph Piacentile v. Sanofi Synthelabo, Inc., No. 05-2927, 2010 WL 5466043 (D.N.J. Dec. 30, 2010), as support for its contention that relator’s kickback claims are not pled with particularity under Rule 9(b).

In Hericks, the Court found that the relator failed to plead with particularity that the defendant provided physicians with kickbacks in the form of free practice management services. Hericks, 2014 WL 1225660, at \*7. The Court reasoned that the relator only provided “a single sentence” description of what those management services were and “nowhere” in the complaint actually “describe[d] a situation” in which those services were provided. Id. at \*6. Further, the relator had “not pointed to a sharp increase in . . . sales other than reference to a chart she received in training, and she has failed to connect the information on this chart with any illegal acts.” Id. at \*9. Similarly, in Piacentile, the Court found that while the relator had alleged an

increase in sales of vials of the drugs at issue following the provision of kickbacks, there was “no mention of how [the relator] knows these vials were used off-label, but baldly states that they were” and that “[o]ther allegations that certain doctors increased their use of [the] drugs are similarly conclusory.” 2010 WL 5466043 at \*8.

In contrast, in U.S. ex rel. Underwood v. Genentech, Inc., 720 F. Supp. 2d 671, 680 (E.D. Pa. 2010), the Court found that the relator had pled kickback allegations related to off-label reimbursement of medications with sufficient particularity. The relator “described the kinds of bribes in some detail” and alleged, without identifying specific actual submissions, that “many thousands of prescriptions were written for Medicare/Medicaid patients, resulting in the presentation of many millions of dollars in false claims to the Government.” Id. The Court concluded that there was no “mystery or ambiguity” to those allegations because the defendant either “lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator’s allegations are sufficiently specific both to inform [the defendant] of the ‘precise misconduct’ charged, and to make it unlikely that Relator has commenced this action in bad faith.” Id.

Here, relator’s kickback allegations are not analogous to those dismissed by the courts in Hericks or Piacentile. Unlike in Hericks, relator alleges with particularity how Cephalon’s kickbacks increased off-label sales of Treanda – namely that Cephalon provided extensive payments and services to induce off-label prescription and tracked the return on investment in terms of increased sales. Unlike in Piacentile, relator does not make conclusory allegations of causation but points to Cephalon’s own statements and documents showing the effectiveness of its alleged kickbacks at increasing off-label sales of Treanda and the existence of programs

allegedly meant to ensure that off-label prescriptions would be reimbursed by government programs.

As discussed above regarding relator's off-label promotion allegations, relator alleges that Cephalon Oncology's In-Practice Program and its advocacy boards provided kickbacks in the form of travel, hotels, meals and cash honoraria to physicians to spread its off-label messaging. Dkt. No. 1-30 at ¶ 217. Cephalon itself allegedly believed that the In-Practice Program and advocacy boards resulted in a 12:1 and 8:1 return on investment in terms of increased Treanda sales respectively. *Id.* at ¶¶ 208, 218. Coupled with the allegations that Cephalon's CORE program aimed at ensuring these increased sales resulted in reimbursement for off-label prescriptions from the government, a program that relator alleges in itself constitutes a kickback, these allegations are sufficient to inform Cephalon of the precise misconduct against it and indicate the action was not commenced in bad faith. *See Seville*, 742 F.2d at 791. Relator's allegations here are significantly more detailed and assert additional factors relevant to causation distinguishing them from the allegations dismissed by the courts in *Piacentile* and *Hericks*. Thus, I will deny Cephalon's motion to dismiss relator's kickback claims.

Finally, because I find that relator "provided sufficient facts to meet the requirements under Rule 9(b)" with regard to his off-label promotion and kickback claims, he has "therefore also met the requirements to state a claim under 12(b)(6)." *Foglia*, 754 F.3d at 158.

## **II. Federal Reimbursement of Treanda for Front-line Treatment of iNHL**

Relator alleges that the off-label prescription of Treanda for front-line treatment of iNHL is not reimbursable under government health programs. *See* Dkt. No. 1-30 at ¶¶ 57-58, 68-69.

Cephalon contends that relator's off-label promotion claims<sup>5</sup> fail because off-label use of Treanda for the front-line treatment of iNHL is federally reimbursable. See Dkt. No. 11 at ECF 9-10. "Whether a use is covered under federal programs generally depends on whether medical items or services are reasonable and necessary." U.S. ex rel. Simpson v. Bayer Corp., No. 05-3895, 2013 WL 4710587, at \*11 (D.N.J. Aug. 30, 2013). Whether prescribing a drug for a particular condition is reasonable and necessary is typically determined by considering whether the drug is prescribed for a "medically accepted indication" that is reimbursable under Medicare and Medicaid. 42 U.S.C. § 1396(b)(i)(1), 1396r-8(k)(9)(2), (3), (6) (Medicaid); 42 U.S.C. § 1395x(t)(2)(A), (B) (Medicare). In turn, whether an indication is medically accepted is determined either by FDA approval or listing in drug compendia, since "the federal government generally will not pay for medications prescribed for purposes not approved by the FDA or 'supported' by any of several pharmaceutical reference books (called 'compendia')." United States v. King-Vassel, 728 F.3d 707, 710 (7th Cir. 2013). Here, since Treanda is not FDA approved for front-line treatment of iNHL, the issue of whether it is reimbursable for that use largely turns on reference to the compendia. The "compendia are large reference books that contain a variety of information about the prescription pharmaceuticals currently available on the American market—everything from their chemical makeup to potential side-effects to the age ranges of patients the drugs have been tested on." Id. at 715, citing Edmonds v. Levine, 417 F. Supp. 2d 1323, 1332-33 (S.D. Fla. 2006). They "seem to be intended primarily for an audience

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<sup>5</sup> Kickback tainted claims would still be "false" under the FCA even if they were reimbursable under Medicare and Medicaid for "medically accepted" indications. See Dkt. No. 1-38 at 20 n.13. Indeed, "[t]he Eastern District also allowed an AKS and off-label-marketing-based FCA claim to survive a motion to dismiss without any discussion of medical necessity due to the marketing being intertwined with illegal kickbacks." U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 369 (E.D. Pa. 2014), citing Underwood, 720 F. Supp. 2d 671, 680.

of health care professionals, but [ ], were specifically incorporated by Congress into the statutory standard for a ‘medically accepted indication.’” Id. at 716.

Under the Medicaid statute, a medically accepted indication is “any use for a covered outpatient drug which is approved under the (FDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the [statutorily named] compendia . . . .” 42 U.S.C. § 1396r-8(k)(6), (g)(1)(B)(i). Medicaid recognizes three compendia, two of which are relevant here: the American Hospital Formulary Service Drug Information (AHFS) and Thomson Micromedex DrugDex (Drugdex). See 42 U.S.C. § 1396r-8(g)(1)(B)(i) (also recognizing United States Pharmacopeia-Drug Information, which apparently ceased publication in 2007). In other words, under the Medicaid statute, coverage should not be denied if the use is supported by the AFHS or Drugdex.

With regard to Medicaid reimbursement, relator contends that the AHFS considered front-line use of Treanda in combination with Rituxan “not fully established” and that DrugDex contained no recommendation concerning the use of Treanda in combination with Rituxan for that indication. Dkt. Nos. 16 at ECF 13-14, 1-38 at 17-20. Cephalon argues that “not fully established” is not equivalent to “not recommended” in the AHFS and that DrugDex permits reimbursement for the front-line use of Treanda to treat iNHL and thus this use is reimbursable under Medicaid. See Dkt. Nos. 1-45 at 9, 1-34 at 17-20.

Under the Medicare statute, off-label use must be supported by a specified compendium and not “be identified as not indicated in one or more such compendia.” 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). In other words, under the Medicare statute, an adverse recommendation in one compendium overrides a positive recommendation in another. Medicare allows for reference to four compendia: (1) the AFHS, (2) the National Comprehensive Cancer Network

(NCCN), (3) Drugdex and (4) Clinical Pharmacology. See Dkt. No. 1-39, Ex. C, Medicare Benefits Manual Ch. 15 § 50.4.5(B). The Medicare Manual considers a use to be medically accepted if it is rated class 1 or 2A under the NCCN, Class I, IIa, or IIb in DrugDex, or is supported by the narrative descriptions in the AHFS or Clinical Pharmacology. See id.

With regard to Medicare reimbursement, relator concedes that both Clinical Pharmacology and NCCN had positive recommendations for Treanda as a front-line treatment of iNHL. Dkt No. 1-30 at ¶ 64. Relator alleges, however, that from the launch of Treanda in December, 2007 until the publication of the Rummel study on February 20, 2013, Treanda was ineligible for reimbursement under Medicare for front-line treatment of iNHL in combination with Rituxan because it was listed as “not fully established” by AHFS. Id. at ¶ 68.

There are at least three important threshold issues regarding drug compendia evidence and whether relator has adequately alleged that Treanda is not reimbursable under federal law for front-line treatment of iNHL to withstand a motion to dismiss. First is a procedural consideration regarding how I should consider drug compendia evidence on a motion to dismiss, since my “job at this stage is not to test the sufficiency of the evidence underlying [the relator]’s allegations or to resolve factual disputes about the meaning of that evidence.” U.S. ex rel. Brown v. Celgene Corp., No. 10-3165, 2014 WL 3605896, at \*6 (C.D. Cal. July 10, 2014). Thus, “the extent to which [a drug compendium] supports any particular off-label use promoted by [a pharmaceutical company], if any, is a fact-specific inquiry that [I am] ill-suited to resolve without a more developed evidentiary record . . . [and] [s]o long as [the relator] alleges facts plausibly suggesting that the uses at issue were not ‘medically accepted,’ [I] must accept her allegations as true.” Id.

This is particularly true with regard to consideration of medical evidence like the compendia, since “[w]hether or not any particular use is ‘supported’ by the compendia is a complex, case-by-case inquiry not susceptible to resolution on a motion to dismiss” and indeed “expert testimony is often necessary to discern whether a mention in a compendium in fact constitutes sufficient support.” Id. at \*5 (declining to decide whether Drugdex supported any particular off-label use on a motion to dismiss); see also Bergman, 995 F. Supp. 2d at 369 (finding that reference to compendia on motion to dismiss did not “resolve as a matter of law (or fact) whether [a drug] was marketed for medically unnecessary uses”); U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc., No. 1:11-00962, 2012 WL 8020674, at \*7 (N.D. Ga. Aug. 29, 2012) (reasoning that the “Defendants’ DRUGDEX evidence is not appropriate for consideration on a motion to dismiss under Rule 12(b)(6)”); U.S. ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 16 (D. Mass. 2008) (finding that “[t]he preliminary record” on a motion to dismiss “is insufficient to determine whether the citations included in DRUGDEX . . . can be read to ‘support’ [a drugs’] off-label use”).<sup>6</sup> For this reason, I am not inclined to resolve the question of whether Treanda was federally reimbursable for off-label uses based upon drug compendia evidence at the motion

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<sup>6</sup> The argument that the Court may take judicial notice of the compendia on a motion to dismiss does not resolve the fundamental issue of whether it is more appropriate to determine the medical reasonableness and necessity of a particular use of a drug based on recommendations in the compendia at the motion to dismiss or summary judgment stage. See U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 369 (E.D. Pa. 2014) (addressing the defendant’s argument that the Court could take judicial notice of the compendia at the motion to dismiss stage but finding that despite having “reviewed and considered these documents” the compendia do not “resolve as a matter of law (or fact) whether [a drug] was marketed for medically unnecessary uses particularly” when there are allegations that the defendants made false or misleading statements about the drug); U.S. ex rel. Brown v. Celgene Corp., No. 10-3165, 2014 WL 3605896, at \*5 (C.D. Cal. July 10, 2014) (noting the argument that the Court could take judicial notice of the drug compendia at the motion to dismiss stage but finding the question of whether the drug compendia support a particular indication is better resolved on summary judgment).

to dismiss stage where relator has made detailed factual allegations in his second amended complaint that Treanda was not reimbursable.

Second, case law in the Eastern District of Pennsylvania implies that “it is sufficient for a relator to allege that an off-label use of a drug is medically risky in order to assume that the relator means the off-label use was medically unnecessary” without reference to drug compendia. Bergman, 995 F. Supp. 2d at 369, citing U.S. ex rel. Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704, at \*12 (E.D. Pa. June 13, 2013) certificate of appealability denied, No. 06-3213, 2013 WL 4511626 (E.D. Pa. Aug. 26, 2013) on recons. in part, No. 06-3213, 2013 WL 5924962 (E.D. Pa. Nov. 5, 2013). The Court in Bergman concluded that the “District of New Jersey’s ruling in Simpson, however, diverges from the Eastern District, [in] finding that off-label uses of drugs may be ‘reasonable and necessary,’ and therefore covered, if those uses are ‘supported by a listing in a major drug compendium.’” Bergman, 995 F. Supp. 2d at 369, citing Simpson, 2014 WL 1418293. Without opining on whether there are different standards in the Eastern District of Pennsylvania and the District of New Jersey regarding the pleading of medical necessity, I will note that here relator has alleged that the off-label use of Treanda was medically risky and that at least under the Court’s reasoning in Bergman that relator’s allegations would constitute a sufficient claim that the off-label use of Treanda for front-line treatment of iNHL is medically unnecessary regardless of any reference to the drug compendia. See Dkt. No. 1-30 at ¶¶ 173-78 (discussing alleged false and misleading information spread by Cephalon regarding the safety risks of off-label use of Treanda).

Third, there is variation among the district courts, including within the Third Circuit, regarding the propriety of deciding FCA claims at the motion to dismiss stage based on drug compendia evidence where there are allegations that the drug compendia themselves were

influenced by false or misleading information promoted by the defendant or tainted by kickbacks. Compare U.S. ex rel. Petratos v. Genentech, Inc., No. 11-3691, 2014 WL 7331945, at \*4 (D.N.J. Dec. 18, 2014) (denying motion to dismiss in part because the relator “allege[d] that Defendant’s actions have compromised the reliability of the various drug compendia entries that list the medically acceptable (and therefore reasonable and necessary) off-label uses of [the drug]”) and Brown, 2014 WL 3605896, at \*6 (denying motion to dismiss in part because the relator alleged the defendant “even tried to improperly influence the compendia by bribing physicians who worked on them”) with Simpson, 2014 WL 1418293, at \*10 (reasoning that “[t]he Court cannot plausibly infer from” allegations of false statements and information promoted by the defendant “that DRUGDEX and the other compendia are unreliable because [the defendant] exerted undue influence”).

Relator alleges that Cephalon took illegal measures to ensure that the off-label use of Treanda gained support in the drug compendia. Dkt. No. 1-30 at ¶ 55. In particular, relator alleges that Cephalon paid kickbacks to the compendium NCCN, including almost \$1.4 million in 2009 in the form of speaker fees and to conduct clinical studies of Treanda. Id. at ¶¶ 251, 252. Indeed, relator alleges that NCCN lists Cephalon as a financial supporter on its website. Id. These allegations, the truth of which is assumed on a motion to dismiss, make resolving whether Treanda is reimbursable under federal government health programs at the pleading stage imprudent.

These threshold considerations all lead me to conclude that Cephalon’s motion to dismiss relator’s claims based on Cephalon’s contention that Treanda was federally reimbursable should be denied. In particular, since this issue involves what is ultimately a factual inquiry into the meaning of “not fully established” in the AHFS, it is not appropriate for resolution at the motion

to dismiss stage. Thus, I will deny Cephalon’s motion to dismiss relator’s claims on reimbursability grounds.

### **III. Reverse False Claims**

Relator alleges that Cephalon made “reverse” false claims in violation of 31 U.S.C. § 3729(a)(1)(G) by failing to comply with the Corporate Integrity Agreement it entered into with the Office of the Inspector General of the U.S. Department of Health and Human Services. Dkt. No. 1-30 at ¶ 353. Relator claims that by failing to report its alleged off-label promotion and payment of illegal kickbacks, Cephalon “engaged in a deliberate plan to knowingly submit false reports to the OIG—as required per the terms of the CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether.” *Id.* at ¶ 342.

Relator alleges that this conduct “avoided or decreased an obligation to pay or transmit money or property to the Government.” *Id.* Section 3729(a)(1)(G) makes liable any person who

knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(1)(G). Relator alleges once in the second amended complaint that Cephalon “improperly avoided or decreased an obligation to pay or transmit money or property to the Government.” Dkt. No. 1-30 at ¶ 342. “However, relator[ ] did not plead any reference to the stipulated-penalties provisions of the CIA[ ] in the SAC and thus provided no factual allegations giving rise to a claim under § 3729(a)(1)(G).” *U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572, at \*12 (E.D. Pa. Apr. 15, 2015), *citing* *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, No. 1:11-029, 2015 WL 1439054, at \*10 (S.D. Ohio Mar. 27, 2015) (finding vague references to obligations to pay under a corporate integrity agreement insufficient under Rule

12(b)(6)). Thus, relator did not “identify a financial obligation or how such an obligation is connected to alleged false CIA reports” in the second amended complaint but only attempted to do so in his briefing. Dkt. No. 18 at ECF 3. Since I test the sufficiency of the allegations in the second amended complaint rather than the sufficiency of relator’s arguments in opposition to the motion to dismiss, I will grant Cephalon’s motion to dismiss relator’s § 3729(a)(1)(G) claim with leave to amend. See id., citing Ibanez, 2015 WL 1439054, at \*10.

#### **IV. First Amendment Protection for Alleged Conduct**

Cephalon contends that off-label promotion of Treanda is commercial speech protected by the First Amendment and cites Sorrell v. IMS Health Inc., 131 S. Ct. 2654, 2671 (2011) and U.S. v. Caronia, 703 F.3d 149, 166 n.10 (2d Cir. 2012) in support of its argument. Both of those cases, however, concerned First Amendment protection for truthful speech and did not consider whether allegedly false and misleading off-label promotion is entitled to First Amendment protection. See Sorrell, 131 S. Ct. at 2672 (reasoning that the State did not “argue that the provision challenged here will prevent false or misleading speech”); Caronia, 703 F.3d at 166 n.10 (“The government does not contend that off-label promotion is in and of itself false or misleading. Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection”). In Bergman the Court rejected the same argument advanced by Cephalon, reasoning that “[f]or commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading.” 2014 WL 348583, at \*14, citing Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 557 (1980) (emphasis in original)). The Court concluded that since the relator had alleged the defendant’s off-label marketing was false and misleading, the defendant’s speech did “not warrant First Amendment protection at [the pleading] stage.” 2014 WL 348583, at \*14. Here, relator has argued that Cephalon’s off-label promotion was based on false and misleading statements. See

Dkt. No. 1-30 at ¶¶ 115, 173. I agree with the Court in Bergman that the question of First Amendment protection is therefore not properly disposed of on a motion to dismiss and will deny Cephalon's motion seeking to dismiss relator's claims on First Amendment grounds.

#### **IV. Conspiracy Claim**

Cephalon argues that relator has failed to state a conspiracy claim under § 3729(a)(3) because he has not sufficiently pled the existence of an agreement between Cephalon and various doctors and organizations to defraud the government. See Dkt. No. 1-34 at 20. Relator contends that his complaint alleges that Cephalon provided inducements to physicians and others in exchange for their agreement to prescribe or induce others to prescribe Treanda. See Dkt. No. 1-38 at 20. "To plead a conspiracy claim under § 3729(a)(3), a plaintiff must allege (1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." Lampkin, 2013 WL 2404238, at \*6. "The essence of a conspiracy under the Act is an agreement between two or more persons to commit a fraud." Piacentile, 2010 WL 5466043, at \*9. A conspiracy claim under the FCA is "required to allege the underlying fraud with particularity, but the allegations of the conspiracy need only satisfy the notice pleading standards of Rule 8." U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., No. 94-7316, 2000 WL 1207162, at \*10 (E.D. Pa. Aug. 24, 2000) aff'd on other grounds sub nom. U.S. ex rel. Atkinson v. PA. Shipbuilding Co., 473 F.3d 506 (3d Cir. 2007); U.S. ex rel. Bartlett v. Tyrone Hosp., Inc., 234 F.R.D. 113, 123 (W.D. Pa. 2006) (agreeing with Atkinson and analyzing a § 3729(a)(3) conspiracy claim under Rule 8(a)).

A meeting of the minds is not sufficiently pled where the relator "merely cites to references to doctors who received speaker's fees and other purportedly improper benefits." Piacentile, 2010 WL 5466043, at \*9. Even where relator has set forth "detailed allegations

regarding specific doctors who received Defendants’ promotional materials and so-called kickbacks” conspiracy is not adequately pled where the relator “nonetheless fails to allege any actual agreement between Defendants and such doctors . . . .” Lampkin, 2013 WL 2404238, at \*6.

While relator has identified with detail the individual doctors who allegedly received kickbacks and engaged in off-label promotion, he has “not alleged that the physicians agreed” to further an illegal off-label promotion scheme. Bartlett, 234 F.R.D. at 124. These claims are also more conclusory while referencing many more actors than the conspiracy allegations asserted against Cephalon I considered in Boise. 2015 WL 1724572, at \*13-14. There, the complaint alleged the existence of a specific formal agreement pursuant to which Takeda Pharmaceuticals and Cephalon allegedly conspired to promote Provigil and Nuvigil off-label, which permitted me to infer allegations of agreement to support relators’ conspiracy claim from relators’ other factual allegations. Id. at \*14. There appears to be no reference to formal agreements here that might allow me to similarly infer allegations of conspiratorial agreement from relator’s conclusory statement of his conspiracy claim. Thus, I will dismiss relator’s conspiracy claim with leave to amend.

## **V. Retaliation Claim**

Relator alleges that Cephalon retaliated against him for his investigation and reporting of Cephalon’s allegedly fraudulent conduct in violation of 31 U.S.C. § 3730(h), which provides:

Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiating of, testimony for, or assistance in an

action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

“A plaintiff asserting a cause of action under § 3730(h) must show (1) he engaged in ‘protected conduct,’ (i.e., acts done in furtherance of an action under § 3730) and (2) that he was discriminated against because of his ‘protected conduct.’” Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 186 (3d Cir. 2001). Relator’s retaliation claim must only meet the pleading standard of Rule 8(a). See U.S. ex rel. Portilla v. Riverview Post Acute Care Ctr., No. 12-1842, 2014 WL 1293882, at \*6 (D.N.J. Mar. 31, 2014). “Determining what activities constitute ‘protected conduct’ is a fact specific inquiry . . . [and] can include internal reporting and investigation of an employer’s false or fraudulent claims.” Hutchins, 253 F.3d at 187.

Relator alleges that Cephalon improperly used its continuing medical education program for marketing purposes and transferred two million dollars from its Sales and Marketing department to its Medical and Scientific Affairs division for that purpose. Relator asserts that he reported his concerns regarding this transfer to Cephalon’s compliance department. Dkt. No. 1-30 at ¶¶ 148, 422-23. Relator contends that soon after reporting his concerns to the compliance department, he was shut out of meetings he had previously attended. Id. at ¶ 423. Second, he alleges he was passed over for a promotion, and that the job was given to a less qualified person as a result of his reporting his concerns. Id. at ¶ 424. Relator alleges that this conduct eventually caused him to resign his position. Id. at ¶ 425. These facts, taken in the light most favorable to relator, sufficiently state a claim for retaliation under § 3730(h) and weigh in favor of allowing discovery so that the fact intensive inquiry required by a retaliation claim under § 3730(h) claim may occur.

## **VI. State Law Claims**

Cephalon moves to dismiss relator's claims under New Mexico and Maryland's qui tam statutes because those states have declined to intervene or otherwise act as statutorily required for relator to maintain a false claims action. Relator concedes that Maryland has declined to intervene. See Dkt. No. 1-38 at 23; Md. Code Ann., Health-Gen. § 2-604(A)(7). The Maryland statute provides that "[i]f the State does not elect to intervene and proceed with the action . . . before unsealing the complaint, the court shall dismiss the action." Id. Thus, I will dismiss relator's Maryland claim.

New Mexico's statute provides in relevant part that:

Within sixty days after receiving a copy of the complaint, the [state] shall conduct an investigation of the factual allegations and legal contentions made in the complaint, [and] shall make a written determination of whether there is substantial evidence that a violation has occurred . . . . If the [state] determines that there is not substantial evidence that a violation has occurred, the complaint shall be dismissed.

N.M. Stat. Ann. § 27-14-7(C). In U.S. ex rel. King v. Solvay S.A., 823 F. Supp. 2d 472, 519-21 (S.D. Tex. 2011) order vacated in part on recons., No. 06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012), the Court concluded that whether New Mexico had made a substantial evidence determination was not properly decided on a motion to dismiss because that determination is necessarily made after a complaint is filed. Thus, the Court reasoned that a relator cannot be required to present evidence of the state's substantial evidence determination at the pleading stage. King, 823 F. Supp. 2d at 519-21.

In contrast to King, here relator filed his initial complaint under seal on August 30, 2010. Dkt. No. 1-2. He filed his operative second amended complaint on July 15, 2013. Dkt. No. 1-30. Thus, relator has had the opportunity to determine and allege in the second amended

complaint whether New Mexico issued him a determination of substantial evidence that its FCA statute was violated. Relator has not done so. I will therefore grant Cephalon's motion to dismiss relator's New Mexico claim with leave to amend.

Cephalon also contends that relator lacks standing to bring a claim under the New Mexico FCA because under that statute only "affected persons" may bring private civil actions. See N.M. Stat. Ann. § 27-14-7(B). Cephalon contends "affected persons" means "New Mexico residents" and that relator is a Pennsylvania resident. The Court in Brown found that there was "no basis . . . to adopt this limited reading of 'affected person'" under the New Mexico statute, reasoning that at least Delaware's FCA expressly defines "affected person" in a much broader sense – "as an 'employee or former employee' of the defendant." 2014 WL 3605896, at \*12. By contrast, the Court in Solvay reached the opposite outcome and found that "affected person" under the New Mexico FCA, while undefined by the statute itself, could refer only to New Mexico residents under the "plain meaning" of the term "affected person." 823 F. Supp. 2d at 521. The Court reasoned there was no basis to think that New Mexico intended to include an understanding of "affected person" as broad as that in the Delaware FCA. Id.

While it might be the case that New Mexico did not intend to adopt as expansive an understanding of "affected person" as Delaware, I conclude that there is similarly no reason offered by either Cephalon or the Court in Solvay to understand "affected person" in the narrowest sense as only referring to New Mexico citizens. Indeed, there is no apparent natural connection between whether a person is "affected" by conduct governed under the New Mexico FCA and New Mexico residency. Thus, I will decline to construe New Mexico's FCA to only provide standing to New Mexico residents.

Finally, Cephalon moves to dismiss relator's state law counts to the extent that relator seeks to allege conduct that occurred before each state statute's effective date. Relator concedes that he does not attempt to apply any state statute to alleged conduct that occurred before the statute's effective date. See Dkt. No. 1-38 at 24. Thus, Cephalon's motion to dismiss relator's state law claims is granted to the extent that they relate to alleged conduct prior to the relevant effective dates of those states' FCA statutes.

### **CONCLUSION**

For the reasons set forth above, I will grant Cephalon's motion to dismiss with regard to relator's conspiracy claim under § 3729(a)(3) with leave to amend, relator's claims under the reverse false claims provision § 3729(a)(1)(G) with leave to amend, relator's claims under Maryland law, relator's claims under New Mexico law with leave to amend and to the extent relator asserts state law claims based on conduct prior to the various state statutes' effective dates. I will deny Cephalon's motion to dismiss in all other respects.

An appropriate Order follows.